I'd like to start by thanking the FDA and this panel specifically for the opportunity to share our views and experiences with Direct-Access Genetic Testing.

23andMe is excited about the future of genetics and the opportunity to work with a wide variety of agencies, organizations, and the medical community at large to establish the regulatory and functional frameworks that will ensure consumers and healthcare professionals are able to access genetic information in a manner that is clear, useful and engaging.

Today, I'm going to cover 23andMe's position on policy and regulation including our requests for this panel's consideration. Tomorrow, you'll hear from my colleague, 23andMe’s Senior Director of Regulatory Affairs and Quality Assurance, Rose Romeo, who will provide more detailed and technical information related to our requests.

23andMe has been proactively collaborating with the FDA for more than a year and we believe we have a clear path to pursue and obtain FDA approval of our entire genetic testing platform, though the process will take time to complete. Today's conversation and this panel's findings will serve to inform our path as we move forward.
Today, I’ll be sharing our views on the following topics…

Topics

• Delivering Information: Analytical & Clinical Validity, Analytical Standards and Transparency
• Putting People First: The Rights of the Public, Patients and Physicians
• (The Impossible Task of) Addressing Fear
• The Benefits of Direct-Access Genetic Testing
• Policy & Regulation: The Essential Elements
• Requests for Consideration
The basis of what every Genetic Testing Service provides is information. It is critical that the information be as accurate and reliable as possible. The information must also be presented in a manner that is clear and transparent so that it is easy for everyone -- physicians, patients and people -- to understand not only what the information can tell them, but also what it can’t.

We have already established comprehensive performance standards and we continually work towards improving them. We also believe that our choice in partners is critical in establishing and maintaining high quality standards, which is why we have continued to utilize the Illumina technology, which we find best in class, and also why we have a strong partnership with National Genetics Institute, a CLIA certified laboratory where clinical genetic testing is frequently and routinely done, to conduct all of our testing.

23andMe believes that the regulatory framework for all genetic testing companies should start with clear and robust analytical performance standards.
It is also important to look at the evolving state of clinical validity for genetic testing applications.

Full genome sequencing is already here. As the technology becomes more affordable and more accessible it’s only a matter of time before we start to see the impact of full sequencing on the clinical validity of genetic tests.

For example, today, clinical validity for Mendelian disorders is fairly well established and result panels are typically based on a specific and known set of genetic mutations related to each disorder. However, full sequencing will impact results for these disorders dramatically as we are able to report on potentially thousands of mutations related to each condition and the specific mutations are likely to vary widely from person to person. Full sequencing is expected to have similar impacts to the clinical validity of pharmacogenetic and disease risk reports as well. As a result, we need to rethink how clinical validity is defined for all genetic testing.

23andMe would like to propose that a collaborative, cross-sector working group be convened to clearly define clinical validity specific to genetic testing. The final definition should reflect the consensus of all relevant government agencies, multiple professional healthcare associations (such as the American Medical Association, American Academy of Family Physicians, and National Association of Nurse Practitioners in Women's Health, among others), academic researchers and representatives from private industry, including pharmaceutical companies and genetic testing service providers.

The future of genetics is clear. The widespread adoption of full sequencing is not long off. 23andMe believes that consumers and healthcare professionals have a right to access the information the latest technology can provide — as long as they are clear about the limitations of that information. As we contemplate regulatory frameworks for genetic services it is important to put regulations in place based on the implications of evolving technologies, a constantly growing knowledge-base about human genetics and the functional realities of genetic testing.
23andMe is currently an industry leader in some of today’s best practices for transparency and clear communication. The following are a few examples from our service.

We provide direct access to our white papers that serve as the basis for the reports we provide to our customers. These include our criteria for including genetic associations in our health reports and our considerations and methodology for how disease risk is calculated, among others.

We are confident in the reports we provide, but it is important that customers can refer directly to source information. In this regard, we provide links to published research on genetic associations and we continually update this information as new research is published.
We are clear about what we test for and what we don’t test for… the use of definitions and disclaimers is particularly important.
The use of graphics and charts in our various reports to visually represent data is an important part of our efforts to ensure information is communicated clearly. We believe these tools can also be equally useful in a clinical setting.

Repetition is also an important element of effective communication, which is why we explicitly remind our customers, in multiple locations across our website, that they should discuss their results with their doctor or other healthcare professional if they have questions about how their results may impact their healthcare.
23andMe believes physicians and other healthcare professionals have an important role to play in Direct Access Genetic Testing and we are committed to working with healthcare organizations to maximize the provider-patient relationship related to genetic testing.

In this regard, we think that the practical implementation of personalized medicine requires an evaluation of the current payor systems and business models for improvements to ensure that access to and use of genetic information is not burdensome on healthcare professionals, our larger healthcare system or consumers.

23andMe is also interested in the collaborative development of CME or other professional education programs for genetic testing together with medical schools and organizations such as the American Medical Association, American Academy of Family Physicians, and the National Society of Genetic Counselors, so that healthcare professionals are prepared to incorporate genetics into their practice.

Finally, we consider ourselves industry leaders with regard to transparency and believe that our experience can help inform the development of regulation. That said, there is always room for improvement. There is an opportunity to better educate people about genetics generally and our customers specifically. In this regard, we would like to work with organizations to maximize comprehension through accessible language. As the industry continues to grow, we may also need to consider providing information in multiple languages.
Ultimately, policy and regulation is meant to protect people -- whether you call them patients or consumers.

We firmly believe that individuals have a fundamental right to directly access information about their own DNA. Empowering people to become informed healthcare consumers is critically important to making the widespread practice of personalized medicine a reality.

We also believe that whenever anyone -- a physician or an individual person -- accesses genetic information they have a right to genetic data that is accurate and reliable.
Protecting the fundamental right of an individual to access his or her genetic information requires addressing some of the more common concerns about Direct-Access Genetic Testing.

23andMe has more than 3 years of customer insight and anecdotal evidence to draw upon. In fact, we now have more than 75,000 genotyped customers and to date, we have no anecdotal evidence to suggest that any of the voiced concerns pose real, demonstrable risk to individuals.

In addition, independent studies conducted by the Genetics and Public Policy Center and Scripps Institutes indicate there is no basis for these concerns. We partnered with the GPPC in their study and are currently teaming up with Robert Green and Scott Roberts on a new study of reactions to personal genomic information.

It is imperative that policy and regulation be based on facts and evidence about how consumers respond to learning directly about their genetic information rather than assumptions about possible irrational consumer behavior and fears that have not been substantiated.
Based on 23andMe’s experience, so much of the conversation about Genetic Testing has been focused on perceived risks and concerns of Direct-Access, so we feel it is important to take a moment to recognize all the various ways Direct-Access Genetic Testing benefits both individuals and the broader field of healthcare.

The benefits of Direct-Access Genetic Testing serve as a foundation to preventive care, which can increase early detection rates, which can be key to effective treatment.

It is also important to recognize that people interact with their genetic information in a variety of ways, and many of these are unrelated to medical decision-making.

### Benefits

**Individuals:**
- Increased awareness of carrier status
- Increased awareness of drug sensitivities
- Shifts mindset to awareness and prevention rather than responding only to symptoms
- Increases likelihood of early detection & possible prevention for some health conditions.
- Enables individuals to actively participate in their health management
- Enables individuals who do not have access to family history to fill in some of the gaps about their health and ancestry
- Objective source of information that disregards perceived ancestry or “known” family history
- Broader use of genetic information beyond medical context
- Direct Access can be cost efficient for consumers – One 23andMe test gives consumers approximately 185 health and trait reports as well as genetic ancestry information
It is only with Direct-Access Genetic Testing that individuals have greater access to participate in medical research as barriers such as time and geography can be removed. Surveys can be completed at the participant’s convenience and the need for physical visits to a research clinic can be eliminated or reduced. Large numbers of participants are critical to advancing our understanding of human genetics.

Our experience shows that when individuals learn about their own genetic data, participating in research becomes more personal and more interesting to them. 23andMe has rates of research participation which far exceed industry standards.

- Of our more than 75,000 genotyped customers 78% have consented to participate in our IRB approved research; and more than 83% of those have answered at least one survey.
- Our Research communities also connect individuals to others with similar conditions and symptoms, providing a sense of community and support.
Direct-Access Genetic Testing itself enables individuals to learn about the basics of genetics through the lens of their own data.

23andMe also provides an engaging and widely available platform for education about genetics.

We started our efforts by focusing on consumers. We have a series of educational videos on our website that are easy to understand and openly accessible. In fact, we’ve posted these videos to YouTube and to-date we’ve had nearly half a million (480,307) views– this does not include viewers who have watched the videos directly on our website.

The next step is to develop CME or other professional education programs, as mentioned earlier, by partnering with various medical associations, professional healthcare organizations and medical schools.
The policy that guides regulation of Genetic Testing services must be flexible enough to keep pace with innovation and rapid technology advancement. It must also accommodate the practical realities of genetic testing and the evolving understanding of the human genome.

On that basis, 23andMe supports regulation that clearly defines high-quality standards of Analytical & Clinical Validity, Analytical Standards, and Transparency.
In conclusion, I leave you with 23andMe’s requests for your consideration:

First, continue to allow informed consumers to freely learn about their own DNA.

Adopt thoughtful **policy** that promotes innovation and is flexible enough to evolve with new technologies and research developments.

Through a cross-sector working group, effectively **define clinical validity** specific to genetic testing.

Finally, focus on **establishing requirements** for analytical and clinical validity, analytical standards and transparency that apply to all genetic testing services. Genetic information provided directly to consumers should be held to the same standards as genetic information provided in a clinical setting.

Thank you all for your time and consideration today.